Translation

## **PCT**

## INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

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Applicant's or agent's file reference 28642P WO/HBwr	FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)				
International application No.	International filing date (day/month/y				
PCT/EP2003/010049	10 September 2003 (10.09.20	003) 10 September 2002 (10.09.2002)			
International Patent Classification (IPC) or n A61L 29/16	ational classification and IPC				
Applicant PROF. DR. JOSEF-PE	TER GUGGENBICHLER, DR.	CHRISTOPH CICHOS GBR			
<ol> <li>This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.</li> </ol>					
2. This REPORT consists of a total of	6 sheets, including this	cover sheet.			
This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).					
These annexes consist of a total of3 sheets.					
3. This report contains indications relating to the following items:					
I Basis of the report					
II Priority					
III Non-establishment	III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability				
· · · ·	IV Lack of unity of invention				
Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement					
VI Certain documents cited					
VII Certain defects in the international application					
VIII Certain observation	Contain alcomotions on the international application				
Date of submission of the demand	Data of som	pletion of this report			
05 April 2004 (05.04)	2004)	09 December 2004 (09.12.2004)			
Name and mailing address of the IPEA/EP	Authorized of	officer			
Pacsimile No.	Telephone N	Jo.			

Form PCT/IPEA/409 (cover sheet) (July 1998)



## INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

### PCT/EP2003/010049

I. Basis of the report							
1. With regard to the elements of the international application:*							
		the inter	national application as originally filed				
	$\boxtimes$	the desc	ription:				
•		pages	1-19	, as originally filed			
		pages		, filed with the demand			
		pages	, filed with the letter of				
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,		pages		, as originally filed			
		pages	, as amended (togethe	r with any statement under Article 19			
		pages		, filed with the demand			
		pages	1-17, filed with the letter of	17 November 2004 (17.11.2004)			
	$\nabla$	the drav	vings.				
		pages	419.019	, as originally filed			
		pages	1/3-3/3	, filed with the demand			
		pages	, filed with the letter of				
	П.	h					
	L! <sup>1</sup>	-	nce listing part of the description:	as originally filed			
		pages pages		, as originally fried			
		pages	, filed with the letter of	, med with the demand			
2.	the in	nternation e elemen	o the language, all the elements marked above were available or furnished to the	nis Authority in the language in which			
	H		guage of publication of the international application (under Rule 48.3(b)).				
			guage of the translation furnished for the purposes of international preliminar	y examination (under Rule 55.2 and/			
3.	With	n regard minary e	to any nucleotide and/or amino acid sequence disclosed in the internation was carried out on the basis of the sequence listing:	ational application, the international			
		contair	ned in the international application in written form.				
	Ц	filed together with the international application in computer readable form.					
	Ш	furnish	ned subsequently to this Authority in written form.				
İ	Щ	furnish	ned subsequently to this Authority in computer readable form.				
	The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in t international application as filed has been furnished.						
	Ш		atement that the information recorded in computer readable form is identica urnished.	It to the written sequence listing has			
4.		The an	nendments have resulted in the cancellation of:				
			the description, pages				
			the claims, Nos.				
ł			the drawings, sheets/fig				
5.			port has been established as if (some of) the amendments had not been made, so the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**	since they have been considered to go			
* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rule 70.16 and 70.17).							
**	* Any	replacen	nent sheet containing such amendments must be referred to under item 1 and ann	nexed to this report.			

## ' INTERNATIONAL PRELIMINATION REPORT

Internation	plication No.
PCT/EP	3/10049

v.	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement					
1.	Statement					
	Novelty (N)	Claims	1-17	YES		
		Claims		NO NO		
	Inventive step (IS)	Claims	1-17	YES		
	* * *	Claims		NO		
	Industrial applicability (IA)	Claims	1-17	YES		
		Claims		NO		

2. Citations and explanations

The present application concerns plastics items which contain in addition to an anti-microbial colloidal metal a soluble or slightly soluble anti-microbial metal salt, and a method for the production thereof.

#### 1. Documents

- 1.1. Reference is made to the following documents:
  - D1: WO 01 24839 A (ACRYMED; GIBBINS BRUCE L (US);
    HOPMAN LANCE D (US)) 12 April 2001 (2001-04-12)
  - D2: WO 01 43788 A (BARD INC C R) 21 June 2001 (2001-06-21)
  - D3: DE 199 36 059 A (GUGGENBICHLER J PETER; HIRSCH ANDREAS (DE)) 1 February 2001 (2001-02-01)
- 1.2. Unless indicated otherwise, the passages of text referred to are those cited in the search report.

#### 2. Novelty

2.1. Document D1 describes a polymer matrix containing silver chloride colloids (see claims 1 and 7 to 9). Copper chloride may also be added for stability.

2.2. Document D2 provides medical items that allow a rapid initial release of anti-microbial metal salts followed by an extended activity phase (page 10, lines 9 to 17). Said items contain colloids consisting of metal salts with differing degrees of water solubility (zinc iodide, silver nitrate, zinc nitrate, silver lactate, silver acetate, silver chloride, etc.) which allow the desired release profile to be set (example 14).

A prefabricated plastics catheter can be treated with the corresponding colloid-metal salt composition (example 15).

- 2.3. D3 concerns catheters that contain colloidal silver and therefore have a high level of anti-microbial activity and improved long-term performance.
- 2.4. None of the documents discloses a combination of anti-microbial colloidal metals with a (soluble or slightly soluble) anti-microbial metal salt. Consequently, the product as per claims 16 and 17 and also the method for producing the product (claims 1 to 15) are novel (PCT Article 33(2)).

#### 3. Inventive step

3.1. Document D3, which is regarded as the closest prior art, discloses prefabricated polyurethane catheters that are treated with a primary metal colloid and are distinguished by the low level of toxicity and at the same time high level of long-lasting antimicrobial activity.

- 3.2. The present application differs from D3 by the further addition of a soluble or slightly soluble anti-microbial metal salt.
- 3.3. The addition of a metal salt produces not only an improved anti-microbial long-term effect, but also a considerably improved immediate effect.
- 3.4. The present invention can therefore be considered to address the problem of "producing plastics products that have improved anti-microbial activity for the entire period of use".
- 3.5. Document D2 looks in detail at the kinetics of various silver salts. By combining various silver salts it is possible to produce catheters that have a rapid initial release as well as a long-term effect. By selecting suitable silver salts, an individual release profile for the silver ions can be set.
- 3.6. D2 does not, however, contain anything that would prompt a person skilled in the art to combine the silver salts from D2 with colloidal silver in order to produce the desired release characteristic. On the contrary, D2 highlights the disadvantages of using metallic silver and asserts that not enough silver is released.
- 3.7. The solution proposed in claim 1 of the present application can therefore be considered inventive (PCT Article 33(3)). The same applies to the item produced according to claims 1 to 15, which is distinguished by a rapid anti-microbial immediate effect within the space of a few hours and also by a

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long-term effect lasting weeks and months.

- 3.8. Consequently, claims 1 to 17 meet the PCT requirements with respect to novelty and inventive step.
  - 4. Industrial applicability
  - 4.1. Claims 1 to 17 of the present application meet the requirements for industrial applicability (PCT Article 33(4)).

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